

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ALERE INC., ALERE SWITZERLAND
GMBH, AND SPD SWISS PRECISION
DIAGNOSTICS GMBH

Plaintiffs-Counterclaim Defendants,

v.

1:10-cv-10027-DPW

CHURCH & DWIGHT COMPANY, INC.,

Defendant-Counterclaim Plaintiff.

JOINT CLAIM CONSTRUCTION AND PRE-MARKMAN HEARING STATEMENT

Plaintiffs, Alere Inc., Alere Switzerland GMBH, and SPD Swiss Precision Diagnostics GMBH (Collectively “Plaintiffs”) and Defendant, Church & Dwight Co., Inc. (“Defendant”) submit the following joint statement regarding claim construction pursuant to the Court’s October 5, 2010 Scheduling Order. The parties do not agree on the number of hours necessary for the hearing nor the order of priority ranking the disputed terms. In addition, there is a dispute as to whether the Court should hear arguments on validity at a claim construction hearing. The parties have agreed on the proper construction of several terms in this action which are identified in Appendix 1 attached hereto. Appendix 1 further identifies those terms in dispute for which the parties have not agreed and the respective constructions proposed by the parties. The parties have also agreed that neither side will present any witnesses at the hearing.

I. PLAINTIFFS' PROPOSAL

A. Anticipated Length of Hearing:

Plaintiffs believe that the Markman hearing can be completed in one day or less (3.5 hours for each party), and are cognizant of the need to use the Court's time efficiently.

B. Tutorial:

Plaintiffs propose to provide a short tutorial on the relevant technology, using PowerPoint slides, an animated demonstrative, graphics and/or poster boards. The tutorial will take 15-30 minutes of Plaintiffs' allotted time.

C. Order of priority ranking of the disputed terms:

394/'378 Patents

- (1) The "Signal" terms: "[a computation circuit, responsive to] a **signal** representing the amount of an analyte or the rate of accumulation of an analyte" ('394 claims 1, 23, 26-27; '378- claim 18); "amount of **signal** accumulation" ('394- claims 22, 24); "the **signal**" ('394- claims 1, 23, 26,27; '378- claim 18)/ "the determined rate or amount of **signal** accumulation" ('394- claim 22, 23, 24, 27)
- (2) The "Threshold" terms: "**first threshold**" ('394- claims 1, 26; '378- claim 18)/"**first threshold** value" ('394- claims 23, 27); "**upper threshold** value" ('394- claims 22, 24) **second threshold**" ('394- claims 1, 26; '378- claim 18)/"**second threshold** value" ('394- claims 23, 27); "**lower threshold** value" ('394- claims 22, 24).
- (3) "means for **comparing**" (claim 22)
- (4) The "result of assay" terms: "**result of an assay**" ('394 claims 1, 22, 23, 24, 27; '378- claim 18)/ "**assay result**"(claim 26); "declaring the **result of the assay**" (claim 23).

- (5) “assay reaches **equilibrium**” (claims 23, 24, 26, 27)
- (6) “means for determining the rate of amount of signal accumulation” (claim 22)
- (7) “at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value” (‘394- claims 22, 24)

‘532 Patent

- (1) The “spaced-apart” zones terms: “**first and second spaced-apart zones** of the liquid transport carrier” (claims 19, 21), “**the first zone** of the liquid transport carrier” (claims 24, 26), “**the second zone** of the liquid transport carrier” (claims 24, 26)
- (2) “[processor configured] to determine a **flow rate** of liquid” (claim 19, 21)
- (3) The “analyte” terms: “**determining** the presence of an **analyte**” (claims 25, 27), “**outputting** a value indicative of the presence of the **analyte**” (claim 27)
- (4) The “sample application zone” terms: “a **sample application zone**” (claim 19), “**first portion** of the liquid transport carrier” (claim 21), “sample receiving zone”(claims 24, 26)
- (5) “selectively illuminate each of the first and second spaced-apart zones” (claim 19)

D. Dispute Concerning Whether the Court Should Hear Argument Concerning Defendant’s Invalidity Contentions:

Contrary to precedent, Defendant intends to argue validity at the claim construction hearing. Plaintiffs object to Defendants attempt to improperly inject validity arguments into the

claim construction process, particularly in this case where the issues have not been fully briefed and would be subject to summary judgment motions.

Defendant has alleged that claims 22 and 24 are invalid for indefiniteness because of the claim term “at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value.” However, defendant did not articulate how the language of the claim is ambiguous such as the claim could not be construed as written. Instead, Defendant’s argument alleged only that there is insufficient written description i.e. that the claim is not supported by the specification. (Def. Opn. Br. 22). In any event, a claim construction hearing is not the proper forum to argue invalidity. *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (holding “[a]mbiguity, undue breadth, vagueness, and triviality are matters which go to claim *validity* for failure to comply with 35 U.S.C. § 112 ¶ 2, not to interpretation or construction.”); *see also*, *L&P Property v. JTM LLC*, 578 F.Supp. 2d 318, 328. fn.5 (D. Mass. 2008) (holding “[a]t this juncture, the court will limit its review to claim construction as L & P has not had the opportunity to fully address defendants' argument [that the claims are invalid as indefinite] in this regard. In any event, this is an issue more appropriately considered at summary judgment.”); *Genentech v. Boehringer Mannheim GmbH*, 989 F.Supp. 359, 367 (D. Mass. 1997) (holding “[t]he troublesome question as to whether the functional definition in the '225 patent is 'hopelessly over-broad,' and meets the requirements of 25 U.S.C. § 112 [sic], is not appropriate for a Markman hearing.”).

A validity challenge whether based on lack of written description or indefiniteness is properly brought in a summary judgment motion. The question of whether claim language complies with the written description requirement involves an underlying question of fact and often requires expert testimony, thus making it generally improper to resolve as part of claim

construction. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (compliance with the “written description” requirement of § 112 is a question of fact, therefore, it may be inappropriate to resolve the issue during claim construction). A validity challenge based on indefiniteness requires the Court to determine that a claim is “insolubly ambiguous.” *Honeywell Int’l, Inc. v. United States*, 609 F.3d 1292, 1301 (Fed. Cir. 2010) requires that the accused infringer show by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim. *Halliburton Energy Servs., Inc., v. M-I LLC*, 514 F.3d 1244, 1249–50 (Fed.Cir.2008). Numerous courts have declined to address indefiniteness arguments at the claim construction stage and have deferred such rulings until the summary judgment stage because of its dispositive effect and the higher burden of proof. *See e.g., T.LG Elecs. U.S.A., Inc. v. Whirlpool Corp.*, No. 09-5142 (GEB-ES), 2011 WL 1560592, at *6 n.3 (D.N.J. Apr. 25, 2011); *Intergraph Hardware Techs. Co. v. Toshiba Corp.*, 508 F.Supp.2d 752, 773 n. 3 (N.D.Cal.2007) (“[The] indefiniteness argument is inappropriate at the claim construction stage.”). Indeed, the Federal Circuit in *Halliburton*, *Exxon*, and *Datamize* reviewed lower court decisions that dismissed the case for indefiniteness at summary judgment, not at a prior *Markman* hearing. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008); *Exxon v. Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1373 9fed. Cir. 2001); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed.Cir.2005).

Finally, the validity dispute as now framed by Defendant has not been briefed and Plaintiffs have not had a chance to fully respond to Defendant’s allegations. Defendant “cannot avoid a full-blown validity analysis by raising the specter of invalidity during the claim construction phase.” *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1346 (Fed. Cir. 1999). Furthermore, as mentioned above, the law is clear that the burden of proof for invalidity is very high, “clear

and convincing,” and this is not the standard for a claim construction hearing. Therefore, the Court should not hear Defendant’s arguments on invalidity at the claim construction hearing. However, should the Court decide to hear argument on validity, Defendant should be limited to the specific arguments included in its claim construction briefs.

II. DEFENDANT’S PROPOSAL:

A. Anticipated Length of Hearing:

Defendant believes the claim construction hearing will more likely require 1½ days.

B. Tutorials:

Defendant also expects to present a tutorial on the relevant technology using up to 30 minutes of its allotted time in the form of PowerPoint slides, animations, graphics, and/or poster boards.

C. Order of priority ranking of the disputed terms:

Defendant’s priority ranking for the ‘394/’378 Patents differs only slightly from Plaintiffs’, primarily the swapping of Plaintiff’s items 4 and 7. Also, for the reasons of efficiency explained below in paragraph D, Defendant proposes to rank the term “*at such time ...*” ahead of the “*means for comparing ...*” terms. Further, though agreeing with Plaintiffs’ ranking for the term, Defendant believes the “*signal*” terms should be broken out as shown below, as the arguments are separate. Thus, Defendant proposes the following priority¹:

‘394/’378 Patents:

- 1) “the signal” (‘394 – claims 1, 23, 26, 27; ‘378 – claim 18);
- “the determined rate or amount of signal accumulation” (‘394 – claims 22, 24)

¹ Once the Court determines the order of priority of the terms, Defendant proposes that the hearing proceed term-by-term.

- 2) “a signal representing the amount of an analyte or the rate of accumulation of an analyte” (‘394 – claims 1, 23, 26, 27; ‘378 – claim 18);
“amount of signal accumulation” (‘394 – claims 22, 24)
- 3) “threshold” terms:
 - “first threshold” (‘394 – claims 1, 26; ‘378 – claim 18);
 - “first threshold value” (‘394 – claims 23, 27);
 - “upper threshold value” (‘394 – claims 22, 24);
 - “second threshold” (‘394 – claims 1, 26; ‘378 – claim 18);
 - “second threshold value” (‘394 – claims 23, 27);
 - “lower threshold value” (‘394 – claims 22, 24)
- 4) “at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value” (‘394 – claims 22, 24)
- 5) “means for comparing the determined rate or amount of signal accumulation with an upper threshold value” (‘394 – claim 22); and
“means for comparing the determined rate or amount of signal accumulation with a lower threshold value” (‘394 – claim 22)
- 6) “equilibrium” (‘394 – claims 23, 24, 26, 27)
- 7) “means for determining the rate or amount of signal accumulation”
(‘394 – claim 22)

8) “result” terms:

“result of an assay” (‘394 – claims 1, 22, 23, 24, 27; ‘378 – claim 18)

“assay result” (‘394 – claim 26)

“declaring the result of an assay” (‘394 – claim 23)

‘532 Patent:

1) “to determine [determining] a flow rate of liquid” (Claims 19, 21)

2) Application zone terms:

“sample application zone” (Claim 19)

“sample receiving zone” (Claims 24, 26)

“first portion of the liquid transport carrier” (Claim 21)

3) “selectively illuminate each of the first and second spaced-apart zones”

(Claim 19)

4) First and second spaced-apart zone terms:

“first and second spaced-apart zones of the liquid transport carrier”

(Claims 19, 21)

“the first zone of the liquid transport carrier” (Claims 24, 26)

“the second zone of the liquid transport carrier” (Claims 24, 26)

5) Presence of analyte terms:

“determining the presence of an analyte” (Claims 25, 27)

“outputting a value indicative of the presence of the analyte” (Claim 27)

D. Dispute Concerning Whether the Court Should Hear Argument Concerning Defendant’s Invalidity Contentions:

Alere argues that invalidity issues cannot be argued during a claim construction hearing, including the issue of indefiniteness with respect to claims 22 and 24 of the ‘394 patent.

However, claim indefiniteness is a matter of, and inseparable from, claim construction, and they are intimately intertwined with each other during claim construction hearings. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008) (“Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction.”)

Consequently, litigants have frequently argued the issue of indefiniteness during claim construction hearings in this, as well as in other districts. *See, e.g., Micro Motion, Inc. v. Krohne, Inc.*, 2011 U.S. Dist. LEXIS 10579 (D. Mass. Feb. 3, 2011); *see also*, Transcript of Markman Hearing Day 1 at 39-58, *Enterasys Networks, Inc. v. Foundry Networks, LLC et al.*, No. 1:05-cv-11298-DPW (D. Mass. Dec. 3, 2010) (Dkt. 207) (J. Woodlock).

In the case at hand, hearing the issue of indefiniteness during claim construction will enhance judicial efficiency. If claims 22 and 24 of the ‘394 patent are found to be indefinite, the Court would not need to expend its time with construction of the term “*at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value*” as well as several other disputed claim terms contained solely within these same claims. Specifically, the terms “*amount of signal accumulation*,” “*means for determining the rate or amount of signal accumulation*,” “*means for comparing the determined rate or amount of signal accumulation with an upper threshold value*,” “*means for comparing the determined rate or amount of signal accumulation with a lower threshold value*,” “*upper threshold value*,” and “*lower threshold value*” would become moot. Therefore, not only can the parties argue the issue of indefiniteness with respect to claims 22 and 24 of the ‘394 patent during the claim construction hearing, they should do so in order to enhance judicial efficiency.

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Respectfully Submitted,

CHURCH & DWIGHT CO., INC.

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